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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,940	03/26/2004	Alisa Ann Ivory	9191ML	1918

27752 7590 02/08/2008  
THE PROCTER & GAMBLE COMPANY  
INTELLECTUAL PROPERTY DIVISION - WEST BLDG.  
WINTON HILL BUSINESS CENTER - BOX 412  
6250 CENTER HILL AVENUE  
CINCINNATI, OH 45224

EXAMINER
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DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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02/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/810,940	Applicant(s) IVORY ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's Request for Continued Examination, amendment and response filed on October 29, 2007 have been received and entered into the case. Claims 1 – 7 and 9 – 19 are pending; claims 14 – 19 are withdrawn; claims 1 – 7 and 9 – 13 have been considered on the merits. All arguments have been fully considered.

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 1 – 7 and 9 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow in view of Yatka et al. (US 5458892 A).

Applicant claims an edible film composition comprising 0.01 – 15% of a fiber agent selected from indigestible dextrin, purified wood cellulose, psyllium, or mixtures thereof; 2 – 75% film forming agent; 0.01 – 30% plasticizing agent; and 0.1 – 60% flavoring agent. The fiber is indigestible dextrin, is present at about 1 – 15% or 5 – 10%; has a length of about 15 – 50 microns or 20 – 35 microns; the film dissolves rapidly in the oral cavity; the film forming agent is present at about 15 – 40%; and is selected from hydroxypropyl cellulose, hydroxypropyl methyl cellulose and mixtures thereof. The composition further comprises a safe and effective amount of a vegetable oil. Applicant additionally claims an edible film composition comprising 0.01 – 25% fiber agent selected from indigestible dextrin, purified wood cellulose, psyllium, or mixtures thereof; 2 – 75% film forming agent; 0.01 – 30% plasticizing agent; 0.1 – 60% flavoring agent; wherein the film rapidly dissolves in the oral cavity and has about 0.001 – 20% or 0.05 – 6% surfactant.

Barkalow teaches an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents, flavoring agents and surfactants (0006,0018) wherein the bulk fillers may be wood cellulose (0048), the film forming agents are hydroxypropyl methyl cellulose (0043). The composition may additionally contain vegetable oils (0065). The bulking agent and film forming agents are present at 10 – 90% (0007,0009), the film forming agents are present at 10 – 90% (0047), the plasticizing agents are present at 0 – 20% (0049), the flavoring is present at .1 – 20% (0062), a surfactant may be present (0018,0060,claim 13), and the composition rapidly dissolves (0032).

Barkalow does not teach the composition wherein the bulk filler agent is indigestible dextrin, purified wood cellulose or psyllium with the claimed length; or wherein the bulking agent encapsulates the flavoring agent. However, at the time of the claimed invention, indigestible dextrin was a known and used bulk filler agent in the art. In support, Yotka teaches a bulking agent that is indigestible dextrin with the claimed length (col.1 line 44-57, col.3). In addition, Yotka teaches that the indigestible dextrin can be dried with flavors to encapsulate the flavor (col.2 line 25-36, col.6 line 13-23). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the indigestible dextrin of Yotka as the bulk filling agent of Barkalow, since it was a recognized bulk filler in the art. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Yotka to substitute indigestible dextrin as the bulk filler in the composition with a reasonable expectation for successfully obtaining the functional edible film of Barkalow.

The references do not teach the composition wherein the exact amounts of each component are present. However as evidenced by the ranges and specific teachings (0068) of Barkalow, it would have been well within the purview of one of ordinary skill in the art to optimize the exact amount of each component as a matter of routine experimentation. Moreover, one of ordinary skill in the art would have been motivated to optimize the various amounts of each component with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 – 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 12 of copending Application No.

10/810,939. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ by amounts of agents, or by parameters such as fiber length and/or viscosity. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to further characterize the specific parameters of the film, to include fiber length and viscosity, as a matter of routine experimentation and practice.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicant argues that Barkalow does not teach the claimed amounts of each component with sufficient specificity; that purified wood cellulose is not disclosed; and that Yatka does not teach dextrin increases the film strength. Applicant further argues that by combine the references, one would obtain a gum not an edible film. Finally applicant states that the provisional double patenting rejection will be addressed upon indication of allowable subject matter.

However, these arguments fail to persuade because Barkalow clearly teaches the claimed amounts as recited in 0047, 0049, 0062, 0009, 0018 and 0060. Regarding sufficient specificity, Barkalow teaches ranges that overlap and include amounts claimed by applicant as well as stating that the amounts may be modified by one in the art (0068). Regarding the wood cellulose, the reference clearly teaches wood cellulose can be used, which would suggest to one in the art that a purified wood cellulose would also be within the scope of the disclosure. It is further noted that the claimed do not absolutely require a purified wood cellulose, but is among several which may be used. Regarding Yatka, the reference is relied upon to demonstrate that dextrin is a commonly used bulk filler in the art and that the reference teaches the same fibers used by applicant. Specifically, fibersol 1, 2 and Pinefiber C. Thus, it is maintained that the reference teaches the claimed fibers and lengths and demonstrates that the instant dextrin was known and used in the art as a bulk filler. Moreover, one of ordinary skill in the art would have been motivated to use the claimed bulk fiber in the film of Barkalow with a reasonable expectation for successfully obtaining an effective edible film.

Applicant's comments regarding the provisional ODP are noted by the examiner.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/  
Primary Examiner  
Art Unit 1651

January 31, 2008